

NOT FOR PUBLICATION

FILED UNDER SEAL

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 04-2355 (JLL) OPINION
---	--

LINARES, District Judge.

This matter comes before the Court by way of Defendant Sun's motion for partial summary judgment seeking a ruling that it is not responsible for any alleged damages to the Plaintiffs prior to the date on which it launched its generic pantoprazole product—January 30, 2008 [Docket Entry No. 1118]. The Court has considered the submissions made in support of and in opposition to the instant motion. No oral argument was heard. Fed. R. Civ. P. 78. Based on the reasons that follow, Defendant's motion is **denied**.

BACKGROUND

1. *General*

This is a patent infringement action to enforce United States Patent No. 4,758,579 ("the '579 patent"). The asserted claims of the '579 patent – claims 22 and 25 – cover a chemical compound named Pantoprazole, and its sodium salt, pantoprazole sodium. Pantoprazole is the

active ingredient in PROTONIX®, a drug manufactured for the treatment of gastric acid disorders (hereinafter referred to as “Protonix”). Plaintiff Nycomed GmbH (formerly known as Altana Pharma AG and, at the time of the invention, Byk Gulden) owns the ‘579 patent. Plaintiff Wyeth (formerly known as American Home Products Corporation) markets and sells Protonix in the United States as Nycomed’s exclusive licensee.

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000. Defendants Teva, Sun and KUDCo each filed an Abbreviated New Drug Application (“ANDA”) pursuant to the Hatch-Waxman Act, seeking FDA approval to sell a generic version of Protonix prior to the expiration of the ‘579 patent.

In May of 2004, Plaintiffs responded by suing Teva, Sun and KUDCo for infringement of the ‘579 patent. In addition to seeking equitable relief, Plaintiffs seek lost profits damages and/or reasonable royalty damages pursuant to 35 U.S.C. §284.

Plaintiffs’ motion for a preliminary injunction was denied in September 2007. Defendants Teva and Sun subsequently launched generic pantoprazole products “at risk,” i.e., before entry of final judgment on the merits of this litigation, and before the patent expired. Sun, Teva and KUDCo each stipulated to infringement of claims 22 and 25 of the ‘579 patent *if* those claims were ultimately found to be valid and enforceable.

A jury trial was conducted for several weeks in April 2010 with respect to Defendant Teva and Defendant Sun’s affirmative defenses and counterclaims that claims 22 and 25 of the ‘579 patent are invalid for obviousness and obviousness-type double patenting. Simultaneously, a non-jury trial was conducted with respect to Defendant KUDCo’s affirmative defenses and counterclaims. The jury returned a verdict in favor of Plaintiffs as to each issue tried. On July 15, 2010, the Court issued a bench opinion as to Defendant KUDCo. The Court ruled that

KUDCo had not demonstrated by clear and convincing evidence that the asserted claims of the '579 patent are invalid either for obviousness under 35 U.S.C. § 103 or under the judicially created doctrine of obviousness-type double patenting. The parties subsequently began discovery on the remaining issues in the case—damages and Defendants' claims of unenforceability.

The '579 patent expired on July 19, 2010. The FDA awarded Wyeth a period of pediatric exclusivity that expired on January 19, 2011.

2. *Sun's Motion*

Defendant Sun now moves for partial summary judgment seeking a ruling that Plaintiffs are precluded, as a matter of law, from seeking any damages from Sun prior to January 30, 2008—the date on which Sun launched its generic pantoprazole product. In particular, Sun seeks a ruling that (a) Plaintiffs cannot impute their alleged lost profits damages to Sun's importation or sale of its product to Caraco in December 2007, (b) Sun cannot be held liable for Caraco's actions prior to January 30, 2008, and (c) and even if Sun could be held liable for Caraco's actions prior to January 30, 2008, Caraco's acts before that date did not constitute infringing "offers to sell" under the patent laws. Plaintiffs oppose Sun's motion on the basis that: (a) whether Sun is responsible for Caraco's acts does not affect the amount of Plaintiffs' damages that flowed from Sun's own infringing acts, to which Sun has stipulated, (b) there is ample evidence that Caraco engaged in infringing offers for sale before January 30, 2008, and (c) at the very least, there is a material dispute of fact as to whether Caraco was acting as Sun's agent during that time period.

A. *Facts Relevant to Sun's Motion*

Plaintiff Nycomed owns the '579 patent. (SUMF, ¶ 15; RSUMF, ¶ 15).¹ In 1997, predecessors of Nycomed and Plaintiff Wyeth entered into a License Agreement wherein Nycomed granted Wyeth an exclusive license to market and sell pantoprazole in the United States. (SUMF, ¶ 16; RSUMF, ¶ 16). *See generally* October 11, 2012 Opinion, Docket Entry No. 1209. Consistent with this agreement, Wyeth filed a New Drug Application with the FDA, seeking authorization to market Protonix in the United States. The FDA approved Wyeth's application on February 2, 2000. (SUMF, ¶ 17; RSUMF, ¶ 17).

On April 6, 2004, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") filed an Abbreviated New Drug Application (ANDA) with the FDA seeking to market a generic version of Protonix prior to the expiration of Nycomed's patent. Thereafter, on or about March 1, 2005, Defendant Sun Pharmaceutical Industries, Ltd. ("Sun"), a public company incorporated under the laws of India, filed its own ANDA, which likewise sought the FDA's approval to sell a generic version of Protonix prior to the expiration of Nycomed's patent. (SUMF, ¶¶ 10, 21; RSUMF, ¶¶ 10, 21).

In response to the ANDAs, Plaintiffs filed separate lawsuits against Teva on May 20, 2004 and Sun on April 13, 2005, claiming infringement of the '579 patent in both actions. (SUMF, ¶ 22; RSUMF, ¶ 22). Caraco Pharmaceutical Labs, Ltd. ("Caraco"), a subsidiary of Sun based in Detroit, Michigan, was also sued by Plaintiffs; Plaintiffs dropped Caraco as a party on March 29, 2009, without prejudice. (SUMF, ¶¶ 12, 13, 23; RSUMF, ¶¶ 12, 13, 23).

¹ "SUMF" refers to Sun's Statement of Undisputed Material Facts. "RSUMF" refers to Plaintiffs' Response to Sun's Statement of Undisputed Material Facts.

Teva received FDA approval of its ANDA on August 2, 2007. Sun received FDA approval on September 11, 2007. (SUMF, ¶ 25; RSUMF, ¶ 25). Sun first shipped its ANDA product to the United States on or around December 18, 2007. (SAF, ¶ 34; RSAF, ¶ 34) (Ruiz Decl., Ex. 71 at 7, Sun's Response to Interrogatory No. 6).

At the beginning of December 2007, Wyeth was the only company selling a pantoprazole product in the United States. (SUMF, ¶ 28; RSUMF, ¶ 28). Teva launched its generic pantoprazole product on December 21, 2007. (SUMF, ¶ 29; RSUMF, ¶ 29). Although the parties dispute precisely when Sun sold its first infringing product in the United States, it is undisputed that Sun officially launched its generic product on the open market on January 30, 2008. (SUMF, ¶ 38; RSUMF, ¶ 38) (RSAF, ¶ 57) (Ruiz Decl., Ex. 63, Velturo Report, ¶ 7).

On January 29, 2008, Sun and Caraco executed a Distribution and Sales Agreement ("DSA") granting Caraco "the exclusive right to market, advertise, promote, distribute, sell, and offer to sell" Sun's generic pantoprazole product in the United States. (SUMF, ¶ 32; RSUMF, ¶ 32). The parties dispute specifically when Sun gave Caraco authorization to begin selling Sun's generic pantoprazole product. According to Sun, Caraco was not authorized to sell Sun's generic pantoprazole product in the United States until January 30, 2008. (SUMF, ¶ 35). According to Plaintiffs, Sun authorized Caraco to sell pantoprazole in the United States as early as December 2007. (RSUMF, ¶ 35). The parties also dispute whether Sun contacted any customers in the United States (other than Caraco) regarding any potential launch of a pantoprazole product at any time prior to January 30, 2008. Sun maintains that it did not. (SUMF, ¶ 36). Plaintiffs maintain that Sun was involved in discussions with Cardinal Health regarding pantoprazole in mid-January 2008. (RSUMF, ¶ 36).

In connection with this action, Sun stipulated that “Sun’s commercial making, using, selling, offering to sell in the United States and/or importing into the United States of generic pantoprazole sodium tablets infringes claims 22 and 25 of U.S. Patent No. 4,758,579, if those claims are valid and enforceable.” (SAF, ¶ 16; RSAF, ¶ 16; Docket Entry No. 617, ¶ 1(d)).

LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant’s favor, there exists no “genuine dispute as to any material fact” and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

The moving party is entitled to judgment as a matter of law when the non-moving party fails to make “a sufficient showing on an essential element of her case with respect to which she has the burden of proof.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). However, if a reasonable juror could return a verdict for the non-moving party regarding material disputed factual issues, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 242-243 (“At the summary judgment stage, the trial judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.”). With this framework in mind, the Court turns now to Sun’s motion.

ANALYSIS

As previously stated, Sun moves for partial summary judgment seeking a ruling that (a) Plaintiffs cannot impute their alleged lost profits damages to Sun’s importation or sale of its

product to Caraco in December 2007, (b) Sun cannot be held liable for Caraco's actions prior to January 30, 2008, and (c) and even if Sun could be held liable for Caraco's actions prior to January 30, 2008, Caraco's acts before that date did not constitute infringing "offers to sell" under the patent laws. Based on the reasons that follow, the Court finds that there are genuine issues of material fact that preclude entry of summary judgment.

1. *Sun's Pre-Launch Activities—Importation*

Plaintiffs' theory of the case as it relates to this motion is that they were directly harmed by the importation of Sun's product beginning in December 2007. In particular, Plaintiffs maintain that: (a) Sun first began shipping infringing pantoprazole into the United States and selling it to Caraco in December 2007, (b) importing and selling are indisputably acts of infringement under 35 U.S.C. § 271(a), and (c) Plaintiffs' claims for price erosion damages flowed directly and foreseeably from those infringing acts by Sun.

In its motion for partial summary judgment, Sun seeks a ruling that Plaintiffs should be precluded from pursuing this theory—namely that they were directly harmed by the importation of Sun's product beginning in December 2007—at trial because: (a) Plaintiffs have failed to introduce any evidence demonstrating that they were damaged by Sun's importation, and (b) Plaintiffs admit they have only quantified lost profits damages resulting from the sales of Sun's product, which began on January 30, 2008.

The Court begins by noting several general principles. First, Sun, as the movant, bears the initial burden of showing that there exists no genuine issue of material fact in dispute and that it is, therefore, entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Celotex*, 477 U.S. at 323. Second, there is no dispute, for purposes of *this* motion, that Plaintiffs may seek damages from Sun beginning on January 30, 2008—the date on which Sun officially launched its

generic product.² Third, Plaintiffs are not seeking lost profits on lost sales from Sun prior to January 30, 2008.³ Rather, Sun's activities during the pre-launch period (of December 2007 through January 29, 2008) are relevant solely with respect to Plaintiffs' claim for price erosion damages.⁴

Thus, the first issue before the Court is whether Plaintiffs should be precluded from seeking price erosion damages from Sun based on Sun's pre-launch activities (from December 2007 through January 29, 2008).

A. *Evidence*

In support of its motion, Sun primarily relies on Plaintiffs' alleged failure to produce evidence of any damage specifically caused by the importation of Sun's product. *See* Reply Br. at 4. In addition, Sun cites to several pieces of evidence contained in the record in support of the position that any such pre-launch importation caused no damaged to the Plaintiffs. For instance, Sun cites to the testimony of Michael Brumfield, one of Plaintiffs' witnesses, who agreed that

² The Court recognizes that Sun has filed, *inter alia*, a separate motion for partial summary judgment seeking a ruling that Plaintiffs are not entitled to lost profits against Sun for lost Protonix sales. As a general matter, said motion raises issues that are distinct from those raised in the instant motion—namely, whether the “legally erroneous methodology employed by Plaintiffs’ damages expert that resulted in Plaintiffs ignoring the existence of Wyeth’s Generic renders Plaintiffs’ entire lost sales theory invalid.” (Docket Entry No. 1194 at 2). Nothing contained in this Opinion should be construed as a dispositive ruling on the issues raised therein.

³ *See* Miller Decl., Ex. JJ, Vellturo Dep. Tr. (May 30, 2012) at 331:10-23 (“I don’t calculate any lost profits on lost sales before January 30th, 2008, with respect to Sun.”); *see also* Pl. Opp’n Br. at 6, n. 4.

⁴ Although the Court construes Plaintiffs’ position as such for purposes of this motion, the Court notes that Plaintiffs’ briefing on the issue is not entirely clear. *Compare* Pl. Opp’n Br. at 6 n. 4 (“Dr. Vellturo made clear in that testimony that his lost profits calculations for lost sales to Sun commenced on January 30, 2008.”) with *id.* (“In any event, as set forth below, the causal chain that led to Plaintiffs’ damages for lost sales on January 30, 2008 began as of Sun’s infringing acts in December 2007.”).

“having a generic product in the warehouse but not agreeing to ship it or sell it” does not drive the price for the brand product down. *See* Miller Decl., Ex. QQ, Brumfield Dep. Tr. (Dec. 13, 2011) at 435:11-17. In addition, Sun relies heavily on the testimony and report of Plaintiffs’ expert, Dr. Vellturo, wherein he admits that he has only quantified lost profits damages resulting from the sales of Sun’s product as of January 30, 2008. *See* Miller Decl., Ex. JJ, Vellturo Dep. Tr. (May 30, 2012) at 331:10-23 (“I don’t calculate any lost profits on lost sales before January 30th, 2008, with respect to Sun.”).

In opposition, Plaintiffs cite to several pieces of evidence to substantiate the alleged scope of Sun’s pre-launch activities. For instance, Plaintiffs cite to evidence in the record suggesting that certain pallets of pantoprazole were shipped by Sun to Caraco with an expected arrival date as early as December 21, 2007. (Ruiz Decl., Ex. 45) (SUN0064106) (“Please verify with the airlines and confirm that 12 pallets have actually been airlifted from Paris and arriving [in] Chicago tonight [December 21, 2007] at 11:30 P.M.”). Plaintiffs also cite to Sun’s Response to Interrogatory No. 6, which indicates that Sun first shipped its ANDA product to the United States on or around December 18, 2007. (SAF, ¶ 34; RSAF, ¶ 34) (Ruiz Decl., Ex. 71 at 7, Sun’s Response to Interrogatory No. 6).

Plaintiffs also cite to an email from “Makarand Sane” of Sun to “Jayesh Shah/Caraco Pharmaceutical Laboratories Ltd.,” which provides that “[w]e are hereby authorizing you to sell the above [shipments of pantoprazole sodium] on behalf of Sun Pharmaceutical Industries Ltd., India. The relevant invoices have been sent to you by separate email. Our formal letter of authorization will follow.” (Ruiz Decl., Ex. 52) (SUN0068380). The email chain is dated December 25, 2007 and the subject line reads “Pantoprazole – Authorization to Sell.” (*Id.*). Attached to the email chain are a series of invoices directed to Caraco dated as early as

December 22, 2007, with a ship-to address of Detroit, Michigan and signed by an “authorised [sic] signatory” of “Sun Pharma Global Inc.” (*Id.*).

Plaintiffs also cite to a purchase order, dated January 15, 2008, listing Caraco Pharmaceuticals as the vendor, S-A-J Distributors as the buyer, “PANTOPRAZOLE SOD DR TAB 40 MG” as the product, and “1/15/2008” as the “ship date.” (Ruiz Decl., Ex. 10, 11 at CAR-KMR0632409). In addition, Plaintiffs submit an “offer letter” sent by Caraco to Rite Aid on January 3, 2008 wherein it offers to sell “pantoprazole sod. 40mg” at the “direct price” of \$225.00, with the caveat that “this offer is valid only if Sun Pharma brings to market Pantoprazole Sodium 40 mg tablets.” (Ruiz Decl., Ex. 12).

In support of the damages element, Plaintiffs rely primarily on calculations prepared by their expert, Christopher Vellturo, Ph.D. In particular, Dr. Vellturo has submitted a report wherein he calculates lost profits on lost sales commencing on January 30, 2008—the date on which Sun officially launched its generic.⁵ In addition, Dr. Vellturo calculates price erosion damages.⁶ According to Dr. Vellturo’s report, “Teva and Sun’s infringement drove down the prices of pantoprazole below levels that would have been obtained ‘but for’ infringement.” (Ruiz Decl., Ex. 63, Vellturo Report, ¶ 155). Dr. Vellturo’s price erosion calculation as it relates to Sun is not limited by the January 30, 2008 date,⁷ and does not quantify the specific effect of

⁵ See Miller Decl., Ex. JJ, Vellturo Dep. Tr. (May 30, 2012) at 331:10-23 (“I don’t calculate any lost profits on lost sales before January 30th, 2008, with respect to Sun.”).

⁶ See generally *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003) (“To recover lost profits on a theory of price erosion, a patentee must show that ‘but for’ infringement, it would have sold its product at a higher price.”).

⁷ See Miller Decl., Ex. II, Vellturo Dep. Tr. (May 30, 2012) at 312:4-14 (“[T]here is a richer impact associated with that infringement that isn’t limited by that date in my analysis.”).

Sun's activities prior to January 29, 2008—including its importation. Rather, any price erosion damages arising out of pre-January 29, 2008 activities by Sun are “subsumed” in Dr. Vellturo's first quarter 2008 assessment.⁸

In reply, Sun construes Plaintiffs position as attempting to “impute the entire amount of lost profits allegedly caused by Sun's sales to the tiny fraction of pantoprazole product that Sun imported in December 2007.” (Reply Br. at 6). It is not clear to the Court—based on the parties' submissions—that Plaintiffs have, in fact, taken this expansive position. In any event, Sun's motion seeks a ruling precluding Plaintiffs from seeking *any* damages from Sun prior to January 30, 2008—the date on which Sun's generic product was launched. Based on the reasons that follow, the Court finds that making such a determination, based on the current record, would be inappropriate.

B. *Analysis*

As previously stated, Plaintiffs seek, *inter alia*, price erosion damages accruing prior to the date on which Sun launched its infringing generic product. Sun moves for partial summary judgment seeking a ruling that Plaintiffs should be precluded from seeking damages for any pre-launch activities based upon Plaintiffs' alleged failure to produce evidence of any damage specifically caused by the importation of Sun's product.

“To recover lost profits on a theory of price erosion, a patentee must show that ‘but for’ infringement, it would have sold its product at a higher price.” *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1378 (Fed. Cir. 2003). Importing a patented invention is an act of infringement under 35 U.S.C. § 271(a). *See generally Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348,

⁸ See Miller Decl., Ex. RR, Vellturo Dep. Tr. (May 30, 2012) at 397:23-398:14 (“[T]he extent of price erosion during that period is subsumed in my first quarter 2008 assessment.”).

1357 n. 3 (Fed. Cir. 2003). Actual damages liability “may accrue before the infringement has been verified or proved in court,” where the loss is “reasonably related to the infringing activity.” *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580 (Fed. Cir. 1992). “Causation is a classical jury question,” as is the measurement of actual damages, including the question of whether the infringer’s premarketing activities caused financial losses to the patent holder. *Id.*

In support of its price erosion claim as to Sun’s pre-launch (i.e., pre-January 30, 2008) activities, Plaintiffs have come forward with, among other things, the following pieces of evidence: (1) an email chain stating that that certain pallets of pantoprazole were shipped by Sun to Caraco (in Chicago) with an expected arrival date as early as December 21, 2007,⁹ (2) Sun’s stipulation, in the context of this action, that its “importing into the United States of generic pantoprazole sodium tablets infringes claims 22 and 25 of U.S. Patent No. 4,758,579, if those claims are valid and enforceable,”¹⁰ (3) Dr. Vellturo’s testimony that “Teva and Sun’s infringement drove down the prices of pantoprazole below levels that would have been obtained ‘but for’ infringement”¹¹ and (4) Dr. Vellturo price erosion calculation as it relates to Sun, which is not limited by the January 30, 2008 date.¹² When viewed in the light most favorable to

⁹ (Ruiz Decl., Ex. 45) (SUN0064106) (“Please verify with the airlines and confirm that 12 pallets have actually been airlifted from Paris and arriving [in] Chicago tonight [December 21, 2007] at 11:30 P.M.”); (SAF, ¶ 34; RSAF, ¶ 34) (Ruiz Decl., Ex. 71 at 7, Sun’s Response to Interrogatory No. 6).

¹⁰ (SAF, ¶ 16; RSAF, ¶ 16; Docket Entry No. 617, ¶ 1(d)).

¹¹ (Ruiz Decl., Ex. 63, Vellturo Report, ¶ 155).

¹² (Miller Decl., Ex. II, Vellturo Dep. Tr. (May 30, 2012) at 312:4-14) (“[T]here is a richer impact associated with that infringement that isn’t limited by that date in my analysis.”).

Plaintiffs, this evidence, if believed by a reasonable jury, could support a claim for price erosion damages as to Sun accruing prior to January 30, 2008.

Thus, the Court finds there to be a genuine dispute of material fact as to whether Sun's pre-launch activities—including the importation of its infringing generic product—caused financial loss to Plaintiffs. Sun's own view that "there are several intervening events that break the causal chain allegedly linking Plaintiffs' claim for damages to the importation" supports this Court's conclusion that this is an issue that must be resolved by the trier of fact. *See Brooktree*, 977 F.2d at 1578 ("As in damage determinations in general, the measurement of actual damages is a question of fact, including the question of whether AMD's premarketing activities caused financial losses to Brooktree. Causation is a classical jury question."); *see generally Bio Tech. Gen. Corp. v. Genentech, Inc.*, 267 F.3d 1325, 1330 (Fed. Cir. 2001) ("The weighing of conflicting evidence is a jury function."). Accordingly, this aspect of Sun's motion for summary judgment is denied.¹³

2. *Caraco's Pre-Launch Activities*

Next, Sun seeks a ruling that Plaintiffs should be precluded from seeking damages from Sun based upon any pre-launch activities by Caraco—a Sun subsidiary and non-party to this action. (SUMF, ¶¶ 12, 13, 23; RSUMF, ¶¶ 12, 13, 23). In particular, Sun argues that: (1) although Sun had shipped its product to Caraco in late 2007, Sun had also instructed Caraco not to sell the product until authorized to do so, (2) this authorization did not occur until January 30, 2008, (3) Caraco expressly recognized that it was not authorized to sell the product until January

¹³ The Court's denial in this regard is without prejudice to Sun's ability to renew this argument at trial if the evidence presented at trial does not rise to the adequate level to sustain a finding that Sun's pre-launch activities caused financial harm to Plaintiffs.

30, 2008, and (4) in any event, Caraco's pre-launch activities do not constitute infringing "offers to sell" pursuant to 35 U.S.C. § 271(a).

Plaintiffs oppose this aspect of Sun's motion on the basis that Sun and Caraco had an agency relationship¹⁴ even before they entered into the Distribution and Sales Agreement (which was signed on January 29, 2008).¹⁵ In the alternative, Plaintiffs argue that there is a genuine dispute of material fact as to: (1) whether Caraco's actions prior to January 30, 2008 constituted infringing offers to sell pursuant to 35 U.S.C. § 271(a), and (2) whether Caraco was acting as Sun's agent when it engaged in such activities.

A. *Relevant Law*

"One corporation whose shares are owned by a second corporation does not, by that fact alone, become the agent of the second company." *Phoenix Canada Oil Co. Ltd. v. Texaco, Inc.*, 842 F.2d 1466, 1477 (3d Cir. 1988); *see generally Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 (3d Cir. 2001) ("[M]ere ownership of a subsidiary does not justify the imposition of liability on the parent"). However, "[w]hen one corporation acts as the agent of a disclosed principal corporation, the latter corporation may be liable on contracts made by the agent." *Phoenix*, 842 F.2d at 1477.

Under traditional agency principles, an agent must have authority to act for the principal. *See, e.g., Bel-Ray Co., Inc. v. Chemrite (Pty) Ltd.*, 181 F.3d 435, 445 (3d Cir. 1999) ("[U]nder traditional agency principles . . . an agent can be bound by the terms of a contract . . . if she is made a party to the contract by her principal acting on her behalf with actual, implied, or apparent authority."); *United States v. Martinez*, 613 F.2d 473, 481 (3d Cir. 1980) ("Actual

¹⁴ Plaintiffs indicate that they are not attempting to impose liability on Sun for the actions of Caraco based on an alter-ego theory. *See Opp'n Br.* at 8 n. 6.

¹⁵ (Miller Decl., Ex. X, SUN0068994).

authority has been defined as (the authority) that the principal expressly or implicitly gave the agent. Apparent authority is power to bind the principal which the principal has not actually granted but which he leads persons with whom his agent deals to believe that he has granted.”) (internal citations and quotations omitted).

When analyzing customary agency principles as a source of parental liability, the Court’s focus centers on the evidence of the relationship between the parent and subsidiary, specifically as it pertains to the plaintiff’s claim of wrongdoing. *See Phoenix*, 842 F.2d at 1477. “[C]omplete domination by the parents in the general conduct of the subsidiaries’ affairs is not a prerequisite” under usual agency principles. *Id.* at 1478. Rather, the issue is whether—even assuming the two companies are unrelated—they might have entered into a limited agency relationship for a specific transaction. *Id.* Whether this has occurred is typically a question of fact. *Id.*

B. *Evidence*

In support of its position that Sun had instructed Caraco not to sell the product until authorized—i.e., January 30, 2008—Sun refers to an email from Daniel Movens, CEO of Caraco, to jshah@caraco.com, dated January 15, 2008, stating: “I want to insure that you have all inventory for this product isolated and it is not in the system. As per our previous discussions we can not [sic] have this product in the system. This will eliminate the accidental shipment of this product which could put us as a company in harms way.” (Miller Decl., Ex. CC, CAR-KMR0013189). According to Sun, this email also demonstrates Caraco’s own recognition that it was not authorized to sell the product it had received from Sun as of January 15, 2008. (Def. Br. at 10).

In support of its position that any pre-launch communications between Caraco and its customers were not infringing offers to sell pursuant to 35 U.S.C. § 271, Sun cites to several

pieces of evidence for the general proposition that Caraco's customer communications, some of which admittedly included receipt of customer purchase orders, were not "confirmed" purchased orders, but rather customer offers to purchase Caraco pantoprazole. For instance, Sun cites to the deposition testimony of Gurpartap Singh Sachdeva, head of sales at Caraco, wherein Sachdeva provides that on January 30, 2008, "we had to go and reconfirm with all the customers because none of the POs received earlier were confirmed POs." (Miller Decl., Ex. DD, Sachdeva Dep. Tr. (June 3, 2011) at 87:19-25).

In opposition, Plaintiffs cite to the email discussed above from "Makarand Sane" of Sun to "Jayesh Shah/Caraco Pharmaceutical Laboratories Ltd.," which provides that "[w]e are hereby authorizing you to sell the above [shipments of pantoprazole sodium] on behalf of Sun Pharmaceutical Industries Ltd., India. The relevant invoices have been sent to you by separate email. Our formal letter of authorization will follow." (Ruiz Decl., Ex. 52) (SUN0068380). The email chain is dated December 25, 2007 and the subject line reads "Pantoprazole – Authorization to Sell." (*Id.*).

Plaintiffs cite again to a "PURCHASE ORDER" dated January 15, 2008 listing Caraco Pharmaceuticals as the vendor, S-A-J Distributors as the buyer, "PANTOPRAZOLE SOD DR TAB 40 MG" as the product, and "1/15/2008" as the "ship date." (Ruiz Decl., Ex. 10, 11 at CAR-KMR0632409). In addition, Plaintiffs submit an "offer letter" sent by Caraco to Rite Aid on January 3, 2008 wherein it offers to sell "pantoprazole sod. 40mg" at the "direct price" of \$225.00, with the caveat that "this offer is valid only if Sun Pharma brings to market Pantoprazole Sodium 40 mg tablets." (Ruiz Decl., Ex. 12).

C. *Analysis*

Having carefully considered the evidence presented, the Court finds that there is a genuine dispute of material fact as to whether Caraco was acting as Sun's agent prior to January 30, 2008. Although Sun has come forward with evidence suggesting that Caraco was aware that it had no authorization to sell the generic product prior to January 30, 2008,¹⁶ Plaintiffs, in opposition to Sun's motion, have forward with evidence upon which a reasonable jury could conclude that Sun was acting as Caraco's agent as early as December 2007. This evidence includes: (1) the December 25, 2007 email from Makarand Sane of Sun to Jayesh Shah of Caraco, containing "Pantoprazole – Authorization to Sell" in the subject line, and stating "[w]e are hereby authorizing you to sell the above [shipments of pantoprazole sodium] on behalf of Sun Pharmaceutical Industries Ltd., India. The relevant invoices have been sent to you by separate email. Our formal letter of authorization will follow;"¹⁷ and (2) the January 15, 2008 purchase order listing Caraco as the vendor, S-A-J Distributors as the buyer, pantoprazole as the product and January 15, 2008 as the ship date.¹⁸ When viewed together, and in the light most favorable to the Plaintiffs, a reasonable juror could conclude that Caraco began acting as Sun's agent in the context of the sale of its generic pantoprazole product as early as December 25, 2007. *See Phoenix*, 842 F.2d at 1478 (noting that whether two unrelated companies might have entered into a limited agency relationship for a specific transaction is a question of fact); *see generally Al- Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1317 (Fed. Cir. 1999) ("As the finder of fact, the jury receives deference for its function of weighing witness demeanor, credibility, and meaning.").

¹⁶ (Miller Decl., Ex. CC, CAR-KMR0013189; Ex. DD, Sachdeva Dep. Tr. (June 3, 2011) at 87:19-25).

¹⁷ (Ruiz Decl., Ex. 52) (SUN0068380).

¹⁸ (Ruiz Decl., Ex. 10, 11 at CAR-KMR0632409).

Next, having found a genuine dispute of material fact as to whether Caraco was acting as Sun's agent prior to January 30, 2008, the Court must determine whether any of Caraco's pre-launch communications could, in any event, be construed by a reasonable jury as an "offer for sale" within the meaning of 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

"As a matter of federal statutory construction . . . price quotation letters can be regarded as 'offer[s] to sell' under § 271 based on the substance conveyed in the letters, i.e., a description of the allegedly infringing merchandise and the price at which it can be purchased." *3D Sys., Inc. v. Aarotech Labs., Inc.*, 160 F.3d 1373, 1379 (Fed. Cir. 1998); see *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1376 (Fed. Cir. 2005). The Federal Circuit has expressly recognized that a price quotation letter can be regarded as an offer to sell even when it states—*on its face*—that it is "not" an offer. *Id.* ("The price quotation letters sent by Aaroflex to California residents state on their face that they are purportedly not offers, but to treat them as anything other than offers to sell would be to exalt form over substance."). In doing so, the Court explained that "[o]ne of the purposes of adding 'offer[] to sell' to § 271(a) was to prevent exactly the type of activity Aaroflex has engaged in, i.e., generating interest in a potential infringing product to the commercial detriment of the rightful patentee." *Id.*

The Court finds that the offer letter sent by Caraco to Rite Aid on January 3, 2008, when viewed in the light most favorable to the Plaintiffs, could be construed by a reasonable jury as an "offer for sale" within the meaning of 35 U.S.C. § 271(a). (Ruiz Decl., Ex. 12). This letter sent by Caraco to Rite Aid offers to sell "pantoprazole sod. 40mg" at the "direct price" of \$225.00. In other words, it contains a description of the allegedly infringing merchandise *and* the price at

which it can be purchased. On its face, this offer letter could be construed as an “offer” which Rite Aid could make into a binding contract by simple acceptance. *See 3D Sys.*, 160 F.3d at 1379 (“[T]he price quotation letters can be regarded as ‘offer[s] to sell’ under § 271 based on the substance conveyed in the letters, i.e., a description of the allegedly infringing merchandise and the price at which it can be purchased.”); *MEMC*, 420 F.3d at 1376 (finding no evidence of an “offer for sale” where, unlike the price quotation letters in *3D Systems*, the e-mails at issue, “while containing a description of the allegedly infringing wafers, do not contain any price terms. Accordingly, on their face, the e-mails cannot be construed as an “offer” which Samsung Austin could make into a binding contract by simple acceptance.”).

Although the offer letter goes on to state that “this offer is valid only if Sun Pharma brings to market Pantoprazole Sodium 40 mg tablets,” based on the Federal Circuit’s decision in *MEMC*¹⁹ and *3D Systems*,²⁰ as discussed above, the Court concludes that the January 3, 2008 “offer letter” could, nevertheless be construed by a reasonable jury as an “offer for sale” within the meaning of 35 U.S.C. § 271(a). *See 3D Sys.*, 160 F.3d at 1379 (“If we were to permit potential infringers to avoid jurisdiction by denominating what otherwise would be an offer to sell merely by asserting the contrary in the offer, the prohibition added to § 271(a) against offers to sell would be hollow indeed.”). Thus, the Court finds there to be a genuine dispute of material fact as to whether Caraco’s pre-January 30, 2008 communications were infringing “offers to sell” within the meaning of 35 U.S.C. § 271(a).

¹⁹ 420 F.3d 1369, 1376 (Fed. Cir. 2005).

²⁰ 160 F.3d 1373, 1379 (Fed. Cir. 1998).

CONCLUSION

For the reasons set forth above, Sun's motion for partial summary judgment [Docket Entry No. 1118] seeking a ruling that it is not responsible for any alleged damages to the Plaintiffs prior to the date on which it launched its generic pantoprazole product—January 30, 2008—is denied. An appropriate Order accompanies this Opinion.



Jose L. Linares
United States District Judge

Date: December 20, 2012